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John Howard, MD
Director
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Robert A. Taft Laboratories, MS-C34
3676 Columbia Parkway
Cincinnati, OH 45226

Attn: Docket No. CDC-2014-0005; NIOSH-272: Respiratory Protective Devices Used in Healthcare

Dear Dr. Howard:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to respond to the Request for Information (RFI) from the National Institute for Occupational Safety and Health on respiratory protective devices used in healthcare. APIC is a nonprofit, multi-disciplinary organization whose mission is to create a safer world through prevention of infection. Our 15,000 members collaborate closely with occupational health professionals in healthcare facilities to develop exposure control plans, educate healthcare workers regarding respiratory protection, and ensure proper protocols are in place to prevent occupational exposures. Below are our responses to the questions raised in the RFI.

1. Do healthcare stakeholders anticipate expanding the use of respiratory protective devices (RPDs) to include elastomeric air purifying respirators and/or Powered Air Purifying Respirators (PAPRs)?

Based on experiences in the facilities of some of our members, we anticipate that, as PAPRs become cheaper and lighter, healthcare employers may consider expanding PAPR use to alleviate the burden of N95 fit testing, rather than from any appreciable benefit of employee protection. That being said, we have concerns that the use of PAPRs impedes healthcare workers ability to observe and communicate with the patient and other members of the healthcare team affecting patient safety. In addition, PAPRs require routine maintenance and must undergo cleaning and disinfection between users and after use in the room of a patient on contact precautions. For many infectious agents, direct and indirect contact (e.g., with contaminated medical equipment and the environment) plays a substantial role in transmission. Elastomeric air purifying respirators are not appropriate for use in healthcare because they impede communications between healthcare workers (HCW) and between HCW and their patients.

3. For RPDs to be used in surgical and/or non-surgical healthcare environments, should NIOSH consider adding requirements and tests beyond those provided in 42 CFR Part 84 for protection against flammability hazards per 16 CFR 1610, UL 2154, or other appropriate standards? NIOSH seeks evidence related to the performance of existing products (NIOSH-approved, but not FDA-cleared as a

medical device) against this standard and the prevalence and characteristics of actual flammability hazards faced by healthcare workers during patient care (i.e., non-surgical activities).

The National Fire Protection Association's (NFPA) 2012 report "Fires in Healthcare Facilities" (http://www.nfpa.org/research/reports-and-statistics/fires-by-property-type/health-care-facilities/fires-in-health-care-facilities) notes the majority of fires in healthcare occur around cooking. Healthcare workers wearing RPDs would not be at risk in these instances. Adding additional levels of testing would not healthcare workers and could paradoxically affect healthcare workers by slowing supply chains of RPD.

4. For RPDs to be used in surgical and/or non-surgical healthcare environments, should NIOSH consider adding optional, supplemental filtration testing (e.g., ASTM F2101–01 [Bacterial Filtration Efficiency] and ASTM F1215:1989 [Particulate Filtration Efficiency]) in addition to the existing NIOSH filter requirements in 42 CFR Part 84? NIOSH requests evidence related to the performance of existing products (NIOSH-approved, but not FDA-cleared as a medical device) against these alternative filter test methods and the prevalence and characteristics of airborne exposures faced by healthcare workers during patient care (i.e., non-surgical activities). NIOSH seeks comparative results for testing against such candidate supplemental standards versus test results achieved in the existing filter efficiency tests of 42 CFR Part 84.

APIC does not have direct data supporting or opposing adding additional filtration testing. However, the decreasing tuberculosis rates in U.S. healthcare workers using RPDs that have not undergone such testing would suggest these devices do protect healthcare workers from respiratory disease and other pathogens.

APIC is concerned that adding additional parameters to the existing NIOSH respirator approval process could result in a shortage of devices and could have unintended adverse consequences. Changing the approval testing requirements to incorporate additional metrics for all masks would create a temporary shortage of NIOSH-approved N95 masks as previously approved products would need to be re-evaluated for these criteria. This would adversely impact facilities that have fit tested hundreds or thousands of at-risk employees with a mask that might no longer be NIOSH-approved, or only conditionally approved.

Respiratory protection is not the only tool used to protect HCW. Immunizations, immunity verification, patient assessment, cough etiquette, transmission-based precautions, HCW education and personal protective equipment also exist to protect HCW and patients. We believe that all protective tools should be evaluated together to consider the best approaches to protect HCW.

APIC wishes to thank NIOSH for its ongoing efforts to ensure protection of HCW and we look forward to opportunities for continued collaboration.

Sincerely,

Jennie L. Mayfield, BSN, MPH, CIC
2014 APIC President